Compliance & Validation Services
Presents a 3-Day Training Course on:

Temperature Controlled Storage & Transportation of Pharmaceuticals
(Includes Cold Chain)

30 April, 1 & 2 May 2019
Copenhagen Marriott Hotel, Denmark

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Fridges, Freezers, Incubators, Cold Stores, Environmental Chambers, Controlled Temperature Warehouses, Passive & Active Cold Boxes, REEFERs, Temperature Controlled Vehicles

System Design:
- Importance of understanding your operating environments
- Importance of getting your requirements correct (URS) and understanding regulatory guidance
- Examples of systems/equipment available and comparison of performance
- Designing systems that will reliably perform correctly (reducing risk by good design)
- Equipment selection and explaining how systems operate
- Monitoring and mapping equipment, including latest technology
- Analysing risk and mitigating/reducing it by design and correct equipment selection

Qualification:
- Checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ)
- Sensor/data logger selection and number and location of sensors (risk assessments and example location/placement maps) and relating instrument tolerance to acceptance criteria
- Duration of studies for various systems and examples of approaches used, including requirements for empty and loaded state mapping (OQ & PQ)
- Reviewing alarm range, monitoring probe positions, control set points and monitoring/mapping data correlation against qualification data
- Data management and report writing (use of Mean Kinetic Temperature [MKT])
- Approach for mapping of existing facilities (includes facility risk assessments)

Operation:
- On-going Risk Management, Continuous Improvement and performance review
- Managing change and requalification requirements,
- Reuse of transit containers and monitors (management and inspection requirements)
- Evaluating and reporting the temperature data and applying good data management
- Managing non-conformance, e.g. transit temperatures go out of specification or data loggers fail

Course Summary: Temperature Controlled Storage & Transportation of Pharmaceuticals - 30 April, 1 & 2 May 2019 Copenhagen Marriott Hotel, Denmark

This course has been restructured to follow a typical life-cycle approach to the design, qualification and operation of temperature controlled storage and distribution systems. Systems, facilities and equipment have been placed into logical groups, which will be taken through their respective life-cycle (design, qualification and operation). The course aims to cover as many types of systems involved in the storage and distribution of drug products as practicable in the allotted time (controlled temperature and cold chain), taking care not to overload the information. The course includes new sections on operational considerations for each system/facility/equipment group, with ongoing risk management, continuous improvement, data reporting/management and dealing with non-conformance, e.g. failure to include shipment loggers, lost loggers and logger failure. So to sum up the course, we take people through system/equipment/facility design + selection for compliant and consistent operation, how to qualify the systems/equipment/facilities (with example approaches) and then through ongoing operational considerations for compliant and consistent operation.

The course will be presented by industry experts who collectively have worked with storage units, facilities and cold chain distribution for many years. Their considerable hands-on experience and knowledge base will provide learning on current industry best practice, using practical real-life examples. There will be numerous opportunities to put the learning into practice during carefully chosen workshops.

Day-time meals and refreshments together with a drinks reception and course dinner, held on the evening of Day 1, are included in the overall package.

Presenters

Mike James, Training Director, Compliance & Validation Services Limited.: Mike has 25 years experience in the pharmaceutical industry, working in a variety of compliance and validation roles. His experience includes preparation and delivery of national/client-based validation training courses, hands-on validation work, validation project management and regulatory compliance consultancy. Previously, Mike spent four years as the Site Validation Manager for GlaxoSmithKline (GSK) at Speke, where he was responsible for all site validation activities, including the development and maintenance of the Site Validation Programme. Before moving to the pharmaceutical industry he spent 15 years as an industry chemist.

Industry Expert: Our industry expert has worked in the Life Sciences industry for over 16 years, and has spent the past 10 years within the temperature-controlled supply chain sector. He began his career at GlaxoSmithKline before moving to Wyeth Pharmaceuticals, managing the Cold Chain Technology group at their EMEA Cold Chain Centre of Excellence. Our expert has worked on both the supplier and industry side of the industry, working for leading providers of both disposal and reusable passive temperature controlled packaging. He has also worked for a leading provider of temperature data-logging devices. As an active member of the PDA's Pharmaceutical Cold Chain Interest Group, he sits on the European Steering Committee and has chaired and been involved in the authoring of several technical reports and training seminars. Our expert has also worked as a GDP consultant and is a trained Responsible Person.

John Welbourn, Consultancy Director, Compliance & Validation Services Limited: A validation professional with over 30 years experience, John has been responsible for the management and execution of validation projects for many major pharmaceutical companies. He has broad experience in the qualification of equipment, utilities and computerised systems, and thermal mapping to support storage conditions. He has presented at conferences in the UK, Europe and the US and has authored several articles on various aspects of validation. John has contributed to The University of Manchester's, Pharmaceutical Engineering Advanced Training (PEAT) Course and Dublin Institute of Technology's (DIT) MSc. course in Pharmaceutical Process Validation.

Philip de Freitas, Sales Manager at Withnell Sensors Ltd. Philip has over 30 years experience in supplying temperature monitoring/mapping equipment and advice to the pharmaceutical industry. For the last 10 years, he has been providing temperature and humidity validation/monitoring solutions, including wired multichannel loggers, wireless and stand alone loggers, to the Pharmaceutical and Biotech industries. Previously, Philip spent 25 years with Kaye, and was one of their key technical sales representatives in Europe.

Who Should Attend

Individuals to benefit from attending this course include anyone involved in the management, operation, engineering, quality assurance and validation of fridges, freezers, cold stores, cold boxes, incubators, warehouses/intermediate storage facilities and temperature controlled vehicles / transit container. The course will also benefit people involved in distribution management of pharmaceutical products/materials. On leaving the course delegates will: be equipped with the latest regulation and guidelines; have a broad and detailed understanding of the design, construction and qualification of storage and distribution systems; be able to apply and share their new knowledge; improve their individual effectiveness; and look back on an enjoyable experience.

Venue

Marriott Hotel, Copenhagen: The Hotel is close to the city centre and located right at the water's edge of the harbour canal. It is around 8 minutes walk from Copenhagen Central Station and Tivoli Gardens (the Gardens are opposite the station). An excellent location to explore the city from.

Address: Copenhagen Marriott Hotel, Kalvebod Brygge 5, Copenhagen 1560, Denmark
Tel: +45-88-33-99-00

Click on images to visit the Hotel's website

Delegates are kindly requested to arrange their own accommodation. ***Course fees are £1,995.00 (GBP) per delegate.*** ***Accommodation is NOT included in the course fees***

Temperature Controlled Storage & Transportation of Pharmaceuticals - Copenhagen Marriott Hotel, Denmark - Course Programme:

Registration (08:45 to 09:00) – Delegates arrive at the meeting room and sign the attendance register. Each day will include at least 1 interactive workshop.

DAY 1 (Tuesday 30 April 2019)

09:00 Opening/Welcome *[Mike James]*

Introduction to Temperature Controlled Storage & Distribution [Industry Expert]:

- Why do we need to control Storage & Distribution temperature
- Consequences of exceeding temperature limits
- Overview of key regulations and guidance, timeline/history and how it fits together
- Understanding your storage/distribution equipment, systems and processes
- The importance of identifying, evaluating and reducing/ mitigating risks and examples of typical risks involved
- Importance of ensuring storage and distribution are integrated into your quality risk management system
- Regulatory focus and who is responsible ensuring compliance

Design of Fridges, Freezers, Incubators, Environmental Chambers and medium to large Cold Stores *[Mike James]:*

- Importance of getting your requirements correct and the use of risk assessments at an early stage
- How refrigeration systems work and how they are utilised in domestic fridges, pharmaceutical fridges and cold stores
- Fridges and freezer selection
  - Typical examples of what is available and election criteria
  - Pros and Cons and risks associated with various types
  - Risk reduction by design
- Cold store design
  - Cooling systems and air distribution
  - Impact of location, facility layout and risk reduction by design
  - Use of dual systems to reduce the risk from equipment failure
- Control and monitoring considerations and their pros and cons
- Incubator types available, selection criteria and typical performance
- Types of environmental chambers (temperature and relative humidity controlled), selection criteria and performance

Design of large Controlled Room Stores and active and passive transportation equipment/systems *[Industry Expert]:*

- Warehouses
  - Specifying requirements and initial risk assessments
  - Design of modern stores, e.g. the importance of air distribution
  - Risk reduction by good design
  - Modifications to existing non-compliant stores (risk reduction)
  - Monitoring considerations and how they relate to facility design
- Transportation systems
  - Types of systems available, e.g. cold boxes, refrigerated containers (Reefers), refrigerated vehicles, and how they operate
  - Selection criteria (pros and cons)
  - Format (pack configurations)
  - Types of risks associated with each and these may be overcome
  - Route considerations and mode of transport (road, ships, planes)
  - Monitoring system considerations
  - Key design / test data provided by the container supplier
- Passive Temperature Controlled Transport Container Study
  - Prepare real examples of phase change (PCM) and water based pack outs for cold boxes
  - Discuss importance of pre-conditioning the cool packs / PCM's
  - Install temperature monitors and ship the units (CPH to UK)
  - Final data analysis will be supplied after the course

Finish: 17:15; Drinks Reception: 19:00; Course Dinner: 20:00

Day 2 (Wednesday 1 May 2019)

Day 2 Introduction (09:00)

Temperature & Relative Humidity Mapping and Monitoring *[John Welbourn]:*

- Temperature and humidity sensor selection (types available and their relative performance)
- Mapping (qualification studies) and permanent monitoring systems
- Different type of systems currently available, e.g. RF and hard-wired
- Advantages and disadvantages of different types of systems
- Load monitoring devices
- Data management and data integrity of monitoring and mapping data

Monitoring/Mapping Device Demonstration *[Philp de Freitas]:*

- Examples of temperature/humidity loggers
- Latest technology
- Features explained, e.g.: set-up, data capture rates/capacities, data reading and data storage
- General advise for instrument use based on experience, e.g. selection, costs, dos and don'ts and advantages/disadvantages

Qualification/ Validation of fridges, freezers and incubators (small units) *[John Welbourn]*

- Types of checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ (+ URS considerations)
- Deciding on the type of sensor/data logger to use
- Determining the number and location of sensors
- Risk assessments and requirements for empty and loaded mapping
- Typically sensor location/placement maps
- Mapping study duration (OQ and PQ)
- Relating instrument tolerance to acceptance criteria
- Reviewing alarm range, monitoring probe positions, control set points and monitoring/mapping data correlation against qualification data
- Managing data, report writing and monitoring considerations

Qualification/ Validation of Warehouses and Large Cold Stores *[Mike James]:*

- Types of checking and testing required at various stages of qualification, e.g. DQ, IQ, OQ and PQ (+ URS considerations)
- Deciding on the type of sensor/data logger to use
- Determining the number and location of sensors
- Risk assessments
- Typically sensor location/placement maps
- OQ and PQ durations
  - Examples of approaches used
- Requirements for empty and loaded state mapping
- Relating instrument tolerance to acceptance criteria
- Reviewing alarm range, monitoring probe positions, control set points and monitoring/mapping data correlation against qualification data
- Data management and report writing (use of Mean Kinetic Temperature [MKT])
- Approach for mapping of existing facilities

Finish: 17:00

Day 3 (Thursday 2 May 2019)

Day 3 Introduction (09:00)

Qualification of active and passive temperature controlled transportation *[Industry Expert]*

Covers: Active and passive cold boxes, temperature controlled containers (including REEFERS) and temperature controlled vehicles:

- Importance of fully understanding route conditions and realistic transit times
- Challenges involved with using cold boxes and qualifying them
- Controls required to ensure consistent performance of units
- Validation approaches for active and passive temperature transportation units, including reducing some of the burden of qualification using the climatic zone approach and data provided by the container supplier
- Overview of what is required at various stages of the qualification/validation
- Qualification of temperature controlled vehicles using a matrix of data, based on vehicle grouping, temperature mapping, and in-transit load monitoring and storage space monitoring
- Reviewing alarm range, monitoring probe/equipment positions, control set points and monitoring/mapping data correlation against qualification data
- Deciding where transit loggers should be placed
- Data management and report writing
- **OPERATIONAL CONSIDERATIONS**
  - On-going RM and continuous improvement
  - Managing change and requalification requirements, e.g. vehicle changes and transit container changes, and route changes + pack configuration changes
  - Revalidation/qualification requirements
  - Reuse of transit units and management and inspection requirements
  - Managing and reporting of transit temperature data and managing reuse of transit monitors
  - Managing non-conformance

Operational Considerations for Smaller Units *[John Welbourn]:*

- On-going RM and continuous improvement
- Controls required
- Facility (housing the units) and unit maintenance and management
- Managing change and requalification requirements
- Handling of data and dealing with non-conformance
- Performance and qualification reviews/monitoring

Operational Considerations for Warehouses and Cold store Facilities *[Mike James]:*

- On-going risk management (RM) and continuous improvement
- Controls required
- Facility maintenance and management
- Managing change and requalification requirements
- Handling of data and dealing with non-conformance
- Performance and qualification reviews/monitoring

Finish: 16:30

BOOKING DETAILS: Temperature Controlled Storage & Transportation of Pharmaceuticals [Includes Cold Chain]: 30 April, 1 & 2 May 2019 Copenhagen Marriott Hotel, Denmark

How to book on this course:

- The simplest and quickest way is to book online. Please visit/return to the CVS web-site, find the course you are interested in and follow the simple instructions (link included below).
- Alternatively, download a booking form, complete it electronically or print and annotate, and return it to us by fax or email (link and contact details included below).
- Or finally, print out this page, complete the form below by hand and return by fax, email or post.

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Fax: +44 (0)1625 800833 **Tel: +44 (0)1625 500833 or +44 (0)1270 760882** **E-mail: info@candvs.com**

Alternative Booking Form *('*' indicates required fields)*

***Booking Contact Name:**		
***Booking Contact E-mail Address:**		
***Booking Contact Telephone Number:**		
***Company Name & Address:**		
***Billing Address** *(Only complete if different to Company Address)*		
***Delegate Information:**	**Number of delegates:**	**Delegate Name(s):**
Delegate E-mail Address(es): *(if different to booking contact)*		
Special dietary requirements?		
Disability Requirements?		
Company VAT Number (or Sales Tax Number) – *EU Countries Only		
***Method of payment, e.g. card, bank transfer or cheque**		NOTE: For card payments by telephone, please ensure you have entered your telephone number above and we will contact you. Alternatively, call +44 (0)1625 500833 to make your payment. Cheques should be sent with a completed booking form to Compliance & Validation Services Limited, 8 Sedgefield Close, Macclesfield, Cheshire, SK10 2WF, United Kingdom.
Payment Reference (if available)		NOTE: For bank transfer payments we will need a valid reference number or purchase order number to fully confirm the booking.
***Total Fees Due** **£1,995 [GBP]** **per delegate**		NOTE: If your finance centre or delegates are based in the United Kingdom (UK), the course fee will be subject to an additional 20% UK VAT charge (**£2,394** per delegate including UK VAT). For EU Countries where finance centres and delegates are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU delegates, VAT is not applicable.

Booking Terms & Conditions

Booking Confirmation: A booking confirmation will be sent to the delegate or booking contact on receipt of payment, or in the case of bank transfer, following receipt of a valid purchase order reference.

Course Fee & VAT Liability: For the majority of participating countries, VAT will be ZERO rated or not applicable. However, for companies whose finance centre is based in the United Kingdom (location where invoices are managed) or delegates are UK based, the indicated course fee will be subject to an additional 20% UK VAT charge. CVS has to charge this by law. For EU Countries where finance centres and delegates are NOT based in the UK, VAT will be ZERO RATED under the reverse charge rule. For non-EU countries and non-EU delegates, VAT is not applicable.

All participating EU based companies (based on the site location), must provide CVS with a valid VAT/Sales Tax reference number, in order for the booking to be completed. CVS is required by law to collect this information.

Cancellation: Cancellation refunds will depend on how long before the course start date the cancellation is received. The following refund structure will apply, based on the date the cancellation is received by CVS:

- More than 28 days will incur a cancellation fee of £200 GBP per registration and qualify for a refund of the remaining course fees
- Between 28 days and 14 days notice will qualify for a 75% refund
- Between 14 days and 7 days notice will qualify for a 50% refund
- No refund will be given for cancellations received with less than 7 days notice
- Substitutions for registered delegates will be accepted without notice

CVS reserves the right to cancel or reschedule any course and/or change presenters. Please be advised that CVS is not responsible for any airfare and/or hotel penalties or other travel charges that delegates may incur. Where government intervention, military activities, natural phenomenon, strikes or any other circumstances make it impossible or inadvisable to run the course at the designated time and place, the delegate shall waive any claim for damages or compensation except the amount paid for registration after the deduction of actual expenses incurred by CVS in connection with the course that the delegate has registered for and there shall be no future liability on the part of either party.

Please visit our web site for full terms and conditions (see the link at the top of this page).

Please note that by completing the booking form (opposite) you are agreeing to our Terms and Conditions.

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